PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

SIA/MNJ

PCT

To:

PLOUGMANN & VINGTOFT A/S
Sundkrogsgade 9
P.O. Box 831
DK-2100 Copenhagen O
DANEMARK

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	15.10.2004

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
32319 PC 01	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK 03/00512	25.07.2003	26.07.2002

Applicant
OBI APS et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	San Miguel, E Tel. +49 89 2399-7414

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 32319 PC 01	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/DK 03/00512	International filing date *(day/month/year)* 25.07.2003	Priority date *(day/month/year)* 26.07.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/145		
Applicant OBI APS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
20.02.2004	15.10.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Alvazzi Delfrate, S Telephone No. +49 89 2399-7450

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00512

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-16 as originally filed

Claims, Numbers

1-26 filed with telefax on 05.10.2004

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-13,22-26

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1-13,22-26

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	14-18
	No:	Claims	
Inventive step (IS)	Yes:	Claims	14-18
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	14-18
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:
D1: WO-A-00/45702

The document D1 is regarded as being the closest prior art to the subject-matter of claim 14, and shows (the references in parentheses applying to this document):

A system for analysing a venous blood sample (Fig.4), the system comprising:
a blood gas analyzer for
providing values of arterial oxygen saturation (see below "further points") (p.18, l.6), and
measuring values of acid/base status and oxygenation status in the venous blood sample (p.18, l.9-10),
means (p.18, l.16-27) for applying a mathematical model to the values of the arterial oxygenation and the values of acid/base status and oxygenation status in the venous blood sample.

The subject-matter of claim 14 differs from this known document in that the venous blood acid/base status and oxygenation status are converted into arterial blood values.
The problem to be solved by the present invention may be regarded as how to provide a system permitting to avoid the sampling of arterial blood by arterial puncture, which is generally considered a more difficult procedure than sampling a venous blood through a venous puncture.
The essence of the invention resides in the fact that the venous blood acid/base status and oxygenation status obtained through invasive measurement are converted into arterial blood values.

The available prior art documents do not give hint toward a system as defined in claim 14.

The other documents present in the search report are not closer to the invention than the above-mentioned background art.

Independent claim 14 therefore meets the requirements of Articles 33(2)-(4) PCT.
Claims 15 to 18 are dependent on claim 14 and as such also meet the requirements of

the PCT with respect to novelty and inventive step.

Further points

Independent claim 14 does not meet the requirements of Art.6 PCT, for the following reason:
- claim 14 is not supported by the description: on p.9, l.13-14 in fact, a step (2) is defined, relating to the non invasively measurement of arterial oxygen saturation, and not just the "arterial oxygenation" as defined in cl.14. This definition moreover, renders the claim unclear, since if the "values of the arterial oxygenation" would already be provided, than it would not be necessary anymore to convert the venous oxygenation status in arterial blood values;
- the expression "measuring and estimating" values is not clear, since once the values are measured, no need exists to estimate them.

This report has been established as if claim 14 would be directed to "a blood gas analyzer for non-invasively measuring values of arterial oxygen saturation, and measuring values of acid/base status and oxygenation status in the venous sample".

CLAIMS (Amended Oct. 2004)

1. A method of converting venous blood values to arterial blood values, said method comprising the steps of:
- a) providing values of arterial oxygenation,
- b) measuring and estimating values of acid/base status and oxygenation status in a blood sample, the sample being obtained from venous blood,
- c) converting the venous blood values by applying a mathematical model for estimating and/or calculating blood acid/base status and oxygenation status into estimated arterial blood values.

2. A method of converting venous blood values to arterial blood values, said method comprising the steps of:
- b) measuring and estimating values of acid/base status and oxygenation status in a blood sample, the sample being obtained from venous blood,
- a) providing values of arterial oxygenation,
- c) converting the venous blood values by applying a mathematical model for deriving blood acid/base status and oxygenation status into estimated arterial blood values.

3. A method according to any of claims 1-2, said measuring and analyzing comprising the further steps of:
- d) providing an anaerobic venous blood sample,
- e) analysing said anaerobic venous blood sample for evaluating the acid/base status of the venous blood sample, and
- f) analysing said anaerobic venous blood sample for evaluating the oxygenation status of the venous blood sample.

4. A method according to any of claims 1-2, said measuring and analyzing comprising the further steps of:
- d) providing an anaerobic venous blood sample,
- f) analysing said anaerobic venous blood sample for evaluating the oxygenation status of the venous blood sample, and
- e) analysing said anaerobic venous blood sample for evaluating the acid/base status of the venous blood sample.

5. A method according to any of claims 1-4, said method comprising the further step of
- g) providing the arterial oxygenation such as oxygen saturation, pressure or concentration, said further step being performed at any time in relation to any of the steps of claims 1-3.

6. A method according to claim 5, said method comprising the even further step of
- h) simulating the blood acid/base status and oxygenation status of an arterial blood sample by use of mathematical modelling.

7. A method according to claim 6, said method comprising still even further steps of
- i) mathematical modelling comprising simulated addition of oxygen, O_2, to and removal of carbon dioxide, CO_2, from the venous blood sample values in a ratio determined by the respiratory quotient,
- j) said mathematical modelling being performed until the simulated oxygen level is equal to the arterial oxygenation level measured or estimated, and
- k1) calculating the acid/base status and the oxygenation of the arterial blood by applying the result of said modelling.

8. A method according to claim 6, said method comprising still even further steps of
- i) mathematical modelling comprising simulated addition of oxygen, O_2, to and removal of carbon dioxide, CO_2, from the venous blood sample values in a ratio determined by the respiratory quotient,
- j) said mathematical modelling being performed until the simulated oxygen level is equal to the arterial oxygenation level measured or estimated, and
- k2) estimating the acid/base status and the oxygenation of the arterial blood by applying the result of said modelling.

9. A method according to any of claims 1-8, said method comprising a further step of
- l) providing the arterial carbon dioxide level such as carbon dioxide pressure, total concentration or bicarbonate concentration), said further step being performed at any time in relation to any of the steps of claims 1-4.

10. A method according to claim 9, said method comprising an even further step of
- m) simulating the blood acid/base status and oxygenation status of arterial blood sample by use of modelling.

11. A method according to claim 10, said method comprising the still even further steps of
- n) mathematical modelling comprising simulated addition of O_2 to and removing CO_2 from the venous blood sample values in a ratio determined by the respiratory quotient,
- o) said modelling being performed until the simulated carbon dioxide level is equal to the arterial carbon dioxide level measured or estimated, and
- p1) calculating the acid/base status and the oxygenation of the arterial blood by applying the result of said modelling.

12. A method according to claim 10, said method comprising the still even further steps of
- n) mathematical modelling comprising simulated addition of O_2 to and removing CO_2 from the venous blood sample values in a ratio determined by the respiratory quotient,
- o) said modelling being performed until the simulated carbon dioxide level is equal to the arterial carbon dioxide level measured or estimated, and
- p2) estimating the acid/base status and the oxygenation of the arterial blood by applying the result of said modelling.

13. A method according to any of claims 3-12, where the measuring or estimating of the arterial oxygen saturation is done by pulse oximetry.

14. A system for analysing a venous blood sample, the system comprising:

- a blood gas analyzer for

  - providing values of arterial oxygenation, and

  - measuring and estimating values of acid/base status and oxygenation status in the venous blood sample, and

- means for applying a mathematical model to the values of the arterial oxygenation and the values of acid/base status and oxygenation status in the venous blood sample

characterised in that the venous blood acid/base status and oxygenation status are converted into arterial blood values.

15. A system according to claim 14, wherein the arterial blood acid/base status and oxygenation status is calculated or estimated.

16. A system according to claim 14 or claim 15, said system comprising means for measuring arterial oxygenation saturation, where the means preferably is a pulse oximeter.

17. A system according to any of claims 14-16, said system comprising a device for anaerobic sampling, preferably by drawing of a venous blood sample.

18. A system according to claim 14-17 further comprising a computer or a medical device with means for converting the venous blood acid/base status and oxygenation status into arterial blood values.

22. A device for anaerobic drawing of venous blood, said device capable of reducing any residual gases in a blood sample bottle by applying a partial vacuum within the sample bottle.

23. A device for anaerobic drawing of venous blood, said device capable of reducing any residual gases in a blood sample bottle by applying a complete vacuum within the sample bottle.

24. A device for anaerobic drawing of venous blood, said device capable of reducing the effects of any residual gases in a blood sample bottle by using gases with partial O_2 and CO_2 pressures adapted to typical venous values within the sample bottle.

25. A device for anaerobic drawing of venous blood, said device capable of reducing the effects of any residual gases in a blood sample bottle by using one or more inert gases in the sample bottle.

26. A device for anaerobic drawing of blood venous blood, said device capable of reducing any residual gases in a blood sample by dividing the sample bottle into one or more compartments with at least one compartment containing blood only.